

REMARKS

This paper is filed in response to the office action mailed on July 4, 2006. In the office action, claims 1-19 stand rejected; in response claims 20 and 21 have been added and claims 5 and 10 have been amended.

Claims 5-8, 10, 12-14, and 17 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Applicant traverses these rejections.

Specifically, the Office action notes that the broad and narrow rang limitations recited in claim 5 are indefinite. Claim 5 is amended to remove “polyoxyalkylenes” from the Markush group, similar to what is recited in claim 1. Accordingly, the indefiniteness rejection of claims 5-8, 12-14, and 17 should be withdrawn.

The Office action also asserts that the Markush group of claim 10 is indefinite, because “growth factors, thrombus enhancing agents and antimicrobial agents” are not “compositions” as recited in the claim. In response, applicants have amended claim 10 and added claims 20 and 21 so that each of these claims is directed to one of the materials previously listed in the Markush group. Thus, the indefiniteness rejection of claim 10 should be withdrawn.

Turning to the rejections based upon the prior art, the Patent Office rejects claims 1-9, 11-13, and 17-19 under 35 U.S.C. § 102(b) as allegedly being anticipated by Japanese Patent No. 02-182259 (“Yasushi”). Applicant traverses this ground of rejection.

Independent claim 1, as well as claims 2-4, 9-10, 15, and 20-21 dependent directly or indirectly thereon, specifies a biocompatible, hemostatic, cross-linked gelatin composition including, among other things, a sufficient amount of a wetting agent solution incorporated into a cross-linked gelatin to permit uniform wetting of the gelatin in the presence of an aqueous solution.

Independent claim 5, as well as claims 6-8, 12-14, and 17 dependent directly or indirectly thereon, specifies a method for decreasing the hydration time of a hemostatic cross linked composition including, among other things, incorporating a biocompatible wetting agent solution with said cross-linked gelatin.

Independent claim 18 specifies a biocompatible, hemostatic, cross-linked gelatin composition including a sufficient amount of wetting agent solution incorporated into a cross-linked gelatin to permit uniform wetting of the gelatin in the presence of an aqueous solution.

Independent claim 19 specifies a method for decreasing the hydration time of a hemostatic cross linked composition including, among other things, incorporating a biocompatible wetting agent solution with said cross-linked gelatin.

Yasushi fails to disclose or suggest a cross-linked gelatin composition including a sufficient amount of a wetting agent solution incorporated into a cross-linked gelatin to permit uniform wetting of the gelatin in the presence of an aqueous solution, as recited by claims 1-4, 9-10, 15, 18, and 20-21.

In addition, Yasushi fails to disclose or suggest a method that includes incorporating a biocompatible wetting agent solution with said cross-linked gelatin, as recited by claims 5-8, 12-14, 17, and 19.

In fact, Yasushi discloses a hemostatic sticking plaster. As noted in the last paragraph of page 4 of Yasushi, the plaster is formed by: (1) adding a surfactant to an aqueous solution of gelatin; (2) stirring the solution to form a foam and freeze-drying the foam to obtain a sponge; and (3) soaking the sponge in an organic solvent solution containing a cross-linking agent in order to cross-link the gelatin or the like. Significantly, and as also noted in the last paragraph of page 6 of Yasushi, the gelatin is not cross-linked until step (3), where the freeze-dried sponge is soaked in an organic solvent solution containing a cross-linking agent. Consequently, the surfactant of Yasushi is not incorporated into a cross-linked gelatin, as specified in the claims, but instead into a simple gel solution.

The Office action mischaracterizes the prior art in stating that Yasushi discloses a “solution comprising surfactant impregnated into the crosslinked gelatin.” As noted above, the surfactant of Yasushi is impregnated into the gel before the gel is cross-linked, and therefore the surfactant is added to a simple gel, not a cross-linked gel.

Because Yasushi does not disclose each of the elements recited by the claims at issue, it follows that the claims are not anticipated thereby. In addition, Yasushi fails to disclose or suggest that it would be desirable or even possible to incorporate a wetting agent into a cross-linked gelatin, and hence a *prima facie* case of obviousness has not been established. See *In re Sernaker*, 217 U.S.P.Q. 1 (Fed. Cir. 1983) and *Ex parte Clapp*, 227 U.S.P.Q. 972, 973 (Bd. Pat. App. 1985).

Claims 10 and 14-16 stand rejected under 35 U.S.C. §103(a) as allegedly obvious over Yasushi in view of U.S. Patent No. 6,063,061 ("Wallace")¹. Applicant traverses this ground of rejection.

Independent claim 16, as well as claim 17 dependent thereon, recites a kit of parts including, among other things, a pledget consisting of a wetting agent incorporated into a cross-linked gelatin, similar to independent claims 1, 5, 18, and 19 discussed supra. Neither Yasushi nor Armstrong disclose or suggest this element.


The deficiencies of Yasushi are addressed above. Wallace is cited for allegedly disclosing an active agent, an amount of wetting agent in a gel after evaporation of a solvent, sterilizing and packaging the gel composition, and a kit. Wallace in no way teaches or suggests incorporating a wetting agent into a cross-linked gelatin, and therefore no combination of Wallace and Yasushi teaches or suggests all of the elements of claim 16. Consequently, the obviousness rejection of independent claim 16 must be withdrawn.

A check in the amount of \$50.00 to cover the fee for one claim in excess of 20 total claims is submitted herewith.

An early action indicating the allowability of this application is respectfully requested. A change of Power of Attorney and Revocation of Prior Powers is forthcoming. The undersigned verifies that he is authorized to act on behalf of the assignee of the present application.

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Respectfully submitted,

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¹ The Office action incorrectly refers to U.S. Patent No. 6,~~603~~,061 in this rejection. Applicants assume that the Examiner intended to refer to U.S. Patent No. 6,063,061.